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**Subject:** News Update: IRIS Slates Vanadium Study For Release, Advances Other Reviews (InsideEPA)

## Risk Policy Report - 06/23/2015

### IRIS Slates Vanadium Study For Release, Advances Other Reviews

Posted: June 22, 2015

EPA has made the first update in more than a year to the status of chemicals under review in its Integrated Risk Information System (IRIS) program that creates hazard assessments underpinning many agency decisions, with a contested vanadium pentoxide (V2O5) review slated for release this fall and other chemical reviews advancing.

The agency announced the updates on its now-defunct IRISTrack website that listed the status of ongoing IRIS assessments. EPA says it will periodically update the list until it unveils a redesigned IRIS website sometime in the fall, which will provide schedules reflecting the agency's "enhanced" risk review development process. EPA is seeking to improve the IRIS program following a critical National Academy of Sciences (NAS) review in 2011.

The most recently released IRIS report was EPA's final assessment of Libby amphibole asbestos issued last December, following fiscal year 2014 when no IRIS assessments were finalized.

The IRISTrack update says EPA now plans to issue a final V2O5 assessment this fall. The V2O5 assessment has been expected as the first IRIS assessment EPA finalizes in calendar year 2015, and the second since the fiscal year began. The congressional justification document accompanying EPA's FY15 budget request stated that the V2O5 "is anticipated to be complete early in 2015" (*Risk Policy Report*, Feb. 17).

It is unclear why the targeted deadline for V2O5 was not met, although staffing changes within the agency could potentially have contributed to the delay. IRIS' chemical manager for the V2O5 assessment left the IRIS program and moved to the front office of EPA's research and development office to work with Deputy Assistant Administrator Bob Kavlock. And the chief of the IRIS branch managing the assessment left the agency for an academic post, agency sources said last spring (*Risk Policy Report*, April 14).

The new IRIS update adds that the V2O5 "assessment has been revised taking into consideration the public comments and in accordance with the recommendation of the final peer review report. The revised assessment is currently undergoing final agency/interagency science discussion."

The update does not address concerns from industry and the Defense Department, who last year requested the agency seek a second peer review of some portion of the draft assessment.

They also pressed EPA for a decision regarding the date of its stopping rule, part of a process for determining whether and to what extent new information is added to the assessment once it has passed the initial drafting phase. In this case, the request was expected to consider how and whether all results of an industry-military research program are reviewed by IRIS staff before completing the assessment.

Agency and stakeholder sources confirm that IRIS leaders have yet to respond to either request. But the update to the IRIS Assessment Status chart suggests it is unlikely there is time for a second peer review before the targeted deadline for completing the assessment later this year.

**The V2O5 assessment is the only IRIS assessment listed in the status update** with a target deadline for posting a final assessment. Several others, however, are listed at step 4a in the IRIS development process, where EPA will release a draft assessment to the public for comment.

EPA includes targeted deadlines for this step for three assessments: t-Butanol, ethyl tertiary butyl ether (ETBE) and hexahydro-1,3,5-trinitro-1,3,5-triazine (RDX). In each case, EPA estimates that the draft assessment will be released for public comment this summer or fall, and the assessments are meanwhile "being revised in response to comments received during interagency science consultation."

The ETBE assessment is one of a half-dozen assessments caught up in concerns over the validity of data published by an Italian toxicology lab, known as the Ramazzini Institute, which used an unusual whole lifetime study approach in research with lab animals. In 2010, EPA's then Science Advisor Paul Anastas announced that the agency would not use Ramazzini data pertaining to soft cancers -- such as those for leukemias -- in its assessments.

The ETBE assessment had until then relied on Ramazzini data for its determination that "there is suggestive evidence of human carcinogenicity of ETBE based on the only oral cancer bioassay in Sprague-Dawley rats (Maltoni et al., 1999)" (*Risk Policy Report*, June 29, 2010).

The document has since been redrafted with different data, an agency source says. The source declined to provide additional detail.

The IRIS assessment of formaldehyde -- whose critical draft peer review by NAS in 2011 unleashed a torrent of reform efforts upon the IRIS program -- is also listed at step 4a for releasing a public draft. No deadline is estimated.

"A revised assessment is under development to address the 2011 NAS peer review recommendations," the status update says. "A revised assessment will repeat Agency review and interagency science consultation before being released for additional public comment and scheduled for discussion at a future IRIS public science meeting. The revised assessment will undergo peer review by" the EPA Science Advisory Board's Chemical Assessment Advisory Committee.

Another long-pending and controversial IRIS assessment, of inorganic arsenic, remains in the early stages, at step 2, which is agency review. After several rounds of critical comment on earlier drafts of the assessment over the years, EPA sought advice from NAS on how to conduct the assessment. Since the release of NAS' recommendations in 2013, progress on the report has slowed with one of the three arsenic chemical managers leaving the IRIS program.

The status update indicates that before submitting the early draft to internal agency review and comment, IRIS staff will release a revised version of their assessment development plan (ADP) this summer. Further, "two public webinars will be conducted in Summer 2015; one on the ADP and another on dose-response." -- *Maria Hegstad*

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